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Attorneys for Defendant
ALTA BATES SUMMIT MEDICAL CENTER

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

COYNESS L. ENNIX, JR., M.D.,

Plaintiff,

v.

ALTA BATES SUMMIT MEDICAL CENTER,

Defendant.

CASE NO. C 07-2486 WHA

SUPPLEMENTAL DECLARATION OF ALEX HERNAEZ IN SUPPORT OF REPLY TO PLAINTIFF'S OPPOSITION TO DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

DATE: April 24, 2008
TIME: 8:00 a.m.
DEPT: Ctrm. 9, 19th Flr
JUDGE: Hon. William H. Alsup

COMPLAINT FILED: May 9, 2007
TRIAL DATE: June 2, 2008

I Alex Hernaez, declare as follows:

1. I am counsel for Defendant Alta Bates Summit Medical Center ("ABSMC" or "Defendant") in this action. I submit this declaration in support of Defendant's reply to Plaintiff's opposition to Defendant's motion for summary judgment. I have personal knowledge of the facts set forth in this declaration.

2. Attached hereto as **Exhibit 1** is a 05/29/02 letter from Summit Medical Center Institutional Review Board of Physician H produced in discovery by Defendant as part of Physician H's peer review file material.

3. Attached hereto as **Exhibit 2** are true and correct copies of excerpts from the 12/12/07 Deposition of Russell Stanten, M.D. taken by Plaintiff's counsel.

4. Attached hereto as **Exhibit 3** are true and correct copies of excerpts from the 12/13/07 Deposition of Lamont Paxton, M.D. taken by Plaintiff's counsel.

5. Attached hereto as **Exhibit 4** are Summit Medical Staff Bylaws (Article VI only).

6. Attached hereto as **Exhibit 5** are true and correct copies of excerpts from the 05/26/07 Deposition of Coyness L. Ennix, Jr., M.D. taken by Defendant's counsel.

7. Attached hereto as **Exhibit 6** are true and correct copies of excerpts from the 02/26/08 Deposition of Eugene Spiritus, M.D. taken by Defendant's counsel.

8. Attached hereto as **Exhibit 7** is a document from Ennix's peer review records produced in discovery.

9. Attached hereto as **Exhibit 8** is a true and correct copy of a document produced by NMA in response to a subpoena.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct. Executed this 3rd day of April, 2008 at San Francisco, California.

/S/
ALEX HERNAEZ

4832-5194-3682.1

KAUFF MCCLAIN & MCGUIRE LLP
ONE POST STREET
SUITE 2600
SAN FRANCISCO, CA 94104
TELEPHONE (415) 421-3111

EXHIBIT 1

SUMMIT
MEDICAL CENTER
INSTITUTIONAL
REVIEW BOARD

PRIVILEGED AND CONFIDENTIAL
CERTIFIED MAIL RETURN RECEIPT REQUESTED

May 29, 2002

[redacted]

Re: Institutional Review Board Action

Dear [redacted]:

Thank you for your letters dated May 14, May 20, and May 22, 2002, regarding the action that was taken by the IRB on April 30, 2002, to terminate its approval of your clinical activities as a researcher for a period of five years, effective the date of suspension, December 18, 2001. Your letters were discussed at the IRB's meeting on May 28, 2002, and this is the IRB's response.

You have requested information regarding the IRB's "appeal process," indicating that you are entitled to a hearing. You provided a copy of 21 CFR Section 56.113, which states that the IRB's suspension or termination of approval "shall include a statement of the reasons for the IRB's action." You also provided a copy of the FDA's guidelines describing the criteria and hearing rights that apply when it decides to disqualify a clinical investigator from participating in research studies under its jurisdiction.

We agree that 21 CFR Section 56.113 applies to us. This will be discussed below. However, the other materials do not apply to us. They apply only to the FDA, when it takes action under its own authority. Our IRB has separate authority and responsibility for taking such measures as it deems appropriate, independently, to protect patients at this hospital, regardless of whether the FDA, a study sponsor, or any other entity follows the same course.

There are no "hearing rights" when the IRB decides to suspend or terminate its approval of research activities. The only right that is mentioned in 21 CFR Section 56.113 is the right to a statement of reasons. Moreover, 21 CFR Section 56.112, which you did not cite, states that the IRB has final authority over the disapproval of research activities at

the facility where it operates. No other institutional officials, including the Medical Executive Committee or the Board of Directors, can approve research if it has not been approved by the IRB. Therefore, according to federal law, an adverse decision by an IRB cannot be appealed to another body, because the decision cannot be overruled.

That said, the IRB is committed to fair procedure. It has demonstrated this in your case by notifying you of the issues and concerns, and giving you extensive opportunities to address them before it reached its conclusions. The IRB believes that you do know the reasons for its action, which is why the letter to you of April 30, 2002, did not make specific reference to them. However, to assure that your rights are fully respected under 21 CFR Section 56.113, the IRB will confirm and elaborate on the reasons in this letter.

As you will recall, the IRB's initial decision to suspend enrollment in all of your clinical trials, as of December 18, 2001, was precipitated by notice that protocol violations had been discovered in two of the trials. The IRB then asked you for certain information, including a copy of the report you had received from the American College of Surgeons Oncology Group ("ACOSOG") in August, 2001, identifying the deficiencies found during its audit. The audit report was received on January 9, 2002, along with your letter dated December 27, 2001.

The impression given by the correspondence and other materials you had provided earlier was that the deficiencies, while characterized by ACOSOG as "major" in some instances, were merely the result of simple, understandable, mistakes or easily correctable flaws in your record-keeping practices. The audit report, itself, described deficiencies in terms that were far more serious.

There were findings of:

- Patient consent forms being signed after patients were started on study treatment;
- The use of consent forms that were different from the version approved by the IRB;
- Study activities such as "tumor measurements/evaluation of status or disease" and "assessment of baseline arm function" not being performed according to the protocol and not being properly documented;
- Treatment doses being incorrectly administered, calculated and documented, with no verification that chemotherapy was administered; and
- Inconsistent data reporting for treatment administration.

All of the above findings were described in the audit report as being "Major."

With specific reference to your practices of obtaining signatures on consent forms after operative intervention and using unapproved versions of the forms, the ACOSOG auditors commented:

> "This reflects a profound misunderstanding of the meaning of the term 'informed consent,' as well as the procedures for patient registration. Use of Model Informed Consent Forms copied from the protocol rather than IRB approved versions that were available indicates an alarming disregard for the oversight function of the Summit Medical Center IRB." (Emphasis added.)

Under "General Comments," the auditors stated:

> "The overall rating for Patient Case Review is Unacceptable. Immediate suspension is recommended due to serious misunderstandings at this institution with regard to informed consent, IRB oversight and procedures for registration of patients. Adherence to the protocols and provision of source documentation are areas of concern as well."

The IRB acknowledges the efforts you have made since then to show that it would be appropriate to allow your studies to resume. Your completion of an on-line course regarding the protection of human research subjects was very appropriate, certainly as a start. However, the IRB does not see a reasonable basis for concluding that you can be relied upon to adhere to the letter and spirit of the applicable requirements in the near future. There are several reasons for this:

1. As reflected in the audit comments quoted above, your conduct violated the most fundamental principles of clinical research. This could only have occurred in the face of extreme carelessness, or an almost inexplicable misunderstanding of concepts that are clear even to a lay person.

2. The responses that you gave to the auditors and have since given to others, including the IRB, have been inconsistent and lacking in credibility.

   For example, according to the audit report, you told the reviewers that you "misunderstood the information presented in the protocol regarding the procedures for obtaining informed consent, registration and obtaining baseline measurements." You also told them it was your "impression that, because patients must sign their consents to have surgery, it was not necessary (and perhaps undesirable) for [you] to obtain written informed consent to participate in research until after the surgery was completed." The IRB does not see these as plausible, good-faith, responses coming from an experienced clinical investigator.

   In your letter to Dr. Samuel Wells, Group Chair and Principal Investigator for ACOSOG, dated December 3, 2001, you offered a different explanation for your deviations. There, you said that you "mistakenly

allowed" two patients "to sign their consent forms and put the wrong date on them, which was after their first surgery." You went on to say that "the consent form should have been dated before the surgery took place," and claimed that you actually gave the patients the information and had the appropriate discussions with them at that juncture. If anything, this was worse than the comments you made to the auditors, above. It suggested a belief on your part that the proper course would have been to instruct the patients to back-date the signatures on their consent forms, which would have been a falsification of records.

3. It does not appear that you have any real insight into the seriousness of the issues or the importance of adhering to proper research practices prospectively.

You say that you now understand the principles of informed consent and that you have appropriately modified your practices, but the IRB is not convinced that this is true. This is not only because of the nature and gravity of the issues discussed above, but because your ongoing communications continue to demonstrate your inability or unwillingness to appreciate the weight and validity of the concerns.

For example, in your letter to the IRB dated April 18, 2002, you stated that you "do not understand" why the IRB is not allowing you to continue to accrue patients on your studies, and that you would like to know "if other investigators like [yourself] who have had problems with one or two clinical trials have also had all of their trials shut down." You went so far as to express the misplaced belief that you are "being singled out unfairly."

In addition, the "Standard Operating Procedure" accompanying your letter dated May 14, 2002 (which appears to refer to the Z0010 Study), is confusing and shows continuing inattention to the details of proper research recruitment and consent procedures. Section 9 of the document begins by stating that it is the responsibility of the "PI and Co-Investigators" (i.e., you and/or your physician colleagues) to perform a "complete informed consent process," properly obtain the subject's signature on the consent form, and then notify the Study Coordinator of the "consented subject." However, the same section then states, inconsistently, that it is the responsibility of the "Research nurse/coordinator" to "contact patients referred by MD to ascertain participation interest, answer questions, and set an appointment to meet with patient to conduct informed consent process (is not done by MD) prior to registration."

Your most recent letters, dated May 20 and May 22, 2002, urging the IRB to allow you to resume your GP100 Peptide Vaccine Study, do not help your case. They are

misleading, and they further illustrate your failure to comprehend basic principles of clinical research and the IRB's function. They also caused us to realize that your last annual report on this study was inaccurate.

Your May 20 letter indicates that, if the IRB does not grant your request, five patients with metastatic melanoma will have to travel to Bethesda, Maryland, in order to participate in this study for "one more chance" at fighting their disease. We note that this is a randomized study, giving subjects only a 50% chance of receiving the experimental vaccine, so they will not necessarily receive this treatment even if they participate in the study. Interleukin II, which is given to subjects in both arms of the study, is FDA approved and can be given to patients even if they do not participate in the study. In addition, this is a national study, with multiple sites other than Bethesda, including Scottsdale, Arizona. Your May 22 letter requests permission to enroll two more patients. A close reading of the accompanying documentation reveals that there is now an additional study site in Riverside, California, which is even closer.

We also note that, in your December 27, 2001 letter responding to the IRB's request for a status report on all of your studies, you listed two patients as having been enrolled in this study. Both appear to have been given Interleukin II treatment, only. One patient then elected to be followed by his oncologist in Gilroy, and the other is being treated by her oncologist in Walnut Creek. Dire circumstances have not been described in either of these situations, where the patients received standard treatment and local care.

We see, too, that in your last annual report requesting renewal of the IRB's approval of this study, dated March 20, 2001, you stated: "No patients have been enrolled yet." In fact, one of the two patients described above was enrolled ten days before, on March 10, 2001, according to your December 27, 2001 letter. This increases the IRB's concerns about the credibility of the information you present.

Finally, you included an argument that the IRB should allow you to resume your research activities because you are "losing significant business by not being able to treat these patients" and it is "creating financial hardship" for you and your family. First, the IRB's action has not prevented you in any way from treating your patients. You remain free to use any treatment modality you see fit, within the standard of care in the community and the scope of your clinical privileges. Second, and more to the point, it is a gross error for you to think that the IRB might be persuaded to reverse its decision because it is affecting your personal income. The IRB respects your interest in pursuing your professional and financial goals, of course, which is why it has been so careful to proceed fairly in this matter; but a clinical investigator's self-interest can never serve as a basis for approving research which, in the IRB's judgment, would jeopardize the rights and well-being of human subjects. This, like the principles discussed above, should not have to be explained to you.

Your request to re-open the GP100 Peptide Vaccine Study at Summit Medical Center is denied.

The IRB hopes that this letter adequately states the reasons for its action. While there will not be a hearing, you are welcome to respond in writing, if you wish. Any such response will be maintained as part of the IRB's records.

Sincerely,

John Salzman, M.D.
Chairman

JS:va

cc: Annette Shaieb, M.D., President of the Medical Staff
Holly Colin, Director Risk Management, Alta Bates Summit Medical Center
Harry Shulman, Esq., Summit Medical Staff Legal Counsel

EXHIBIT 2

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
--o0o--

COYNESS L. ENNIX, JR., M.D., as an individual and in his representative capacity under Business & Professions Code Section 17200 et seq.,

Plaintiff,

vs. No. C 07-2486

RUSSELL D. STANTEN, M.D., LEIGH I.G. IVERSON, M.D., STEVEN A. STANTEN, M.D., WILLIAM M. ISENBERG, M.D., Ph.D., ALTA BATES) SUMMIT MEDICAL CENTER and Does 1 through 100,

Defendants.

CERTIFIED COPY

CONFIDENTIAL

CONFIDENTIAL PURSUANT TO PROTECTIVE ORDER

DEPOSITION OF
RUSSELL D. STANTEN, M.D.

December 12, 2007

REPORTER: BRANDON D. COMBS, RPR, CSR 12978

the medical record in more lengthy description.

Q. And then the next paragraph, it says that you stated that you thought there was an individual physician skill/judgment issue here. Do you believe that accurately reflects the view you expressed at that meeting?

A. Yes.

Q. And at this time, February 9, 2004, what led you to conclude that there was an individual physician skill/judgment issue?

A. The fact that there had been severe complications in multiple patients and the fact that length of the procedures had been excessively long, and that the people present during the operations felt that they weren't proceeding in a manner that assured them of a satisfactory outcome.

MS. McCLAIN: Excessively, not expressively.

MR. EMBLIDGE: Q. Did you talk to any of the people during these proceedings?

A. I believe without specifically recalling that I had some conversations with some people who were present during those operations.

Q. Can you recall anyone that you talked to?

A. I'd be speculating.

Q. Can you recall anything you did to review

A. My sense of a learning curve of a new procedure is one that may take somewhat longer than normal and for which there may be a higher conversion rate. But I believe that an increase in the number of complications or deaths as a result of that procedure does not constitute a normal learning curve.

Q. You spoke very generally in response to very general questions about complications arising in a short period of time for other surgeons, do you recall that testimony?

A. Yes.

Q. Were the cases you were thinking of in any way comparable to the results of the four surgeries that Dr. Ennix did using the minimally invasive procedure in early 2004?

MR. EMBLIDGE: Objection. Vague, leading and overbroad.

THE WITNESS: No. I believe there were substantial differences between what was referred to in the questioning and what occurred with Dr. Ennix.

MS. McCLAIN: Q. Can you explain to us what you meant by severe complications to multiple patients?

A. In these cases, there were severe technical complications resulting in the need for reoperation in several of the patients, one of which was the valve was

removed and replaced during the operation, one of which the valve was removed and replaced at a second operation, and the third of which the patient died before the valve could be removed and replaced but he clearly needed that.

Q. As you think back over the cases that you were aware of that Mr. Emblidge was questioning you about, is this situation with Dr. Ennix, in your judgment, precedented or unprecedented?

MR. EMBLIDGE: Leading, vague and overbroad.

THE WITNESS: I would say they were unprecedented.

MS. McCLAIN: Q. Finally, you talked about whether or not you had experienced a situation within your limited experience of peer review matters being surfaced to the officer level. And I want to ask you a question about that subject matter.

To your knowledge, do you recall the time when the officers were involved in a peer review process at the cardiothoracic level or the peer -- or the surgery peer review committee level from the beginning of the process other than Dr. Ennix's?

MR. EMBLIDGE: Objection. Vague.

THE WITNESS: I don't recall any other cases of that, no.

STATE OF CALIFORNIA

I do hereby certify that the witness in the foregoing deposition was by me duly sworn to testify the truth, the whole truth, and nothing but the truth in the within-entitled cause; that said deposition was taken at the time and place therein stated; that the testimony of the said witness was reported by me, a Certified Shorthand Reporter and a disinterested person, and was under my supervision thereafter transcribed into typewriting; that thereafter, the witness was given an opportunity to read and correct the deposition transcript, and to subscribe the same; that if unsigned by the witness, the signature has been waived in accordance with stipulation between counsel for the respective parties.

And I further certify that I am not of counsel or attorney for either or any of the parties to said deposition, nor in any way interested in the outcome of the cause named in said caption.

IN WITNESS WHEREOF, I have hereunto set my hand the 27th day of December, 2007.

Certified Shorthand Reporter

CSR No. 12978

EXHIBIT 3

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
--o0o--

COYNESS L. ENNIX, JR., M.D., as an individual and in his representative capacity under Business & Professions Code Section 17200 et seq.,

Plaintiff,

vs. No. C 07-2486

RUSSELL D. STANTEN, M.D., LEIGH I.G. IVERSON, M.D., STEVEN A. STANTEN, M.D., WILLIAM M. ISENBERG, M.D., Ph.D., ALTA BATES) SUMMIT MEDICAL CENTER and Does 1 through 100,

Defendants.

CERTIFIED COPY

CONFIDENTIAL

CONFIDENTIAL

DEPOSITION OF
LAMONT PAXTON, M.D.

December 13, 2007

REPORTER: BRANDON D. COMBS, RPR, CSR 12978

A. To the best of my recollection I believe these were -- we did review data sheets regarding morbidity, mortality numbers, and that may well be what that is.

Q. Do you know who prepared or provided you with those data sheets?

A. The medical staff office.

Q. Do you know the source of the information contained in those data sheets?

A. As I recall, these are numbers that are submitted to the Society for Thoracic Surgery, the STS, and the surgeons submit their data and I believe this is done by cardiothoracic surgeons all over the country, submit their data to the STS which is evaluated and sent back to them. And it's a risk-adjusted evaluation whereby they can compare objectively based on risk assessment, based on illness of the individual patient, their risk-adjusted morbidity/mortality results.

Q. I take it you're aware that the cardiothoracic peer review committee reviews the STS data of the cardiothoracic surgeons at Summit; correct?

A. I would assume they do. I've not attended those meetings.

Q. This is the same information that they looked at that you are now looking at; is that right?

A. I don't know the answer to that.

STATE OF CALIFORNIA

I do hereby certify that the witness in the foregoing deposition was by me duly sworn to testify the truth, the whole truth, and nothing but the truth in the within-entitled cause; that said deposition was taken at the time and place therein stated; that the testimony of the said witness was reported by me, a Certified Shorthand Reporter and a disinterested person, and was under my supervision thereafter transcribed into typewriting; that thereafter, the witness was given an opportunity to read and correct the deposition transcript, and to subscribe the same; that if unsigned by the witness, the signature has been waived in accordance with stipulation between counsel for the respective parties.

And I further certify that I am not of counsel or attorney for either or any of the parties to said deposition, nor in any way interested in the outcome of the cause named in said caption.

IN WITNESS WHEREOF, I have hereunto set my hand the 27th day of December, 2007.

Certified Shorthand Reporter

CSR No. 12978

EXHIBIT 4

BYLAWS

MEDICAL STAFF OF SUMMIT MEDICAL CENTER

****

February 2003

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ARTICLE VI
CLINICAL PRIVILEGES

6.1 EXERCISE OF PRIVILEGES

Except as otherwise provided in these bylaws, a member providing clinical services at this hospital shall be entitled to exercise only those clinical privileges specifically granted. Said privileges and services must be hospital specific, within the scope of any license, certificate or other legal credential authorizing practice in this state and consistent with any restrictions thereon, and shall be subject to the rules and regulations of the clinical department and the authority of the department chairman and the medical staff. Medical staff privileges may be granted, continued, modified or terminated by the board of directors of this hospital only after due consideration of a recommendation of the medical staff, as provided by these bylaws, only for reasons directly related to quality of patient care and other provisions of the medical staff bylaws, and only following the procedures outlined in these bylaws.

6.2 DELINEATION OF PRIVILEGES IN GENERAL

A. Requests

Each application for appointment and reappointment to the medical staff must contain a request for the specific clinical privileges desired by the applicant. A request by a member for modification of clinical privileges may be made at any time, but such requests must be supported by documentation of training, experience and current competence supportive of the request. The applicant shall have the burden of establishing that the applicant has the qualifications and competency necessary to exercise the clinical privileges requested.

B. Bases for Privileges Determination

Requests for the granting and renewal of clinical privileges shall be evaluated on the basis of the member's current competence including education, training, experience, demonstrated professional competence and judgment, clinical performance, and the documented results of patient care and other quality review and monitoring. Privilege determinations may be based in whole or in part, as appropriate, on pertinent information concerning clinical performance obtained from other sources, especially other institutions and health care settings where a member exercises or has exercised clinical privileges.

C. Requests for Modification of Clinical Privileges

A medical staff member who seeks a modification of clinical privileges may submit such a request at any time upon a form developed by the MEC except that such application may not be filed within six (6) months of the time a similar request has been denied.

If additional information is sought from the applicant, he or she shall be responsible for providing it or arranging for it to be provided in the same manner as pertains to applicants pursuant to Section 5.5 B-9 and 5.5 C.

Requests for an increase in privileges must be supported by documentation of sufficient training and experience to support the request. Applications for modification of clinical privileges shall be processed in substantially the same manner as provided in Section 5.7.

6.3 PROCTORING

A. General Provisions

Except as otherwise determined by the MEC, all initial appointees to the medical staff and all members granted new clinical privileges shall be subject to proctoring on an appropriate number of cases as established by the MEC, or the department as designee of the MEC, by the chairman of the department, or the chairman's designee in accordance with the proctoring protocol established by the department to determine suitability to continue to exercise the clinical privileges granted in that department. The member shall remain subject to such proctoring until the credentials committee determines and the MEC agrees that it is no longer necessary based on:

1. a report signed by the chairman of the department(s) to which the member is assigned describing the evaluation of the appointee's performance, a statement that the appointee appears to meet all of the qualifications for unsupervised practice in that department, has discharged all of the responsibilities of staff membership, and has not exceeded or abused the prerogatives of the category to which the appointment was made; and

2. a report signed by the chairman of the other department(s) in which the appointee may exercise clinical privileges, describing the evaluation of the appointee's performance and a statement that the member has satisfactorily demonstrated the ability to exercise the clinical privileges initially granted in those departments.

B. Medical Staff Advancement

The failure to obtain any specific clinical privileges shall not, of itself, preclude advancement in medical staff category of any member, provided a sufficient scope of privileges is obtained to facilitate competent and complete patient care within the primary specialty.

6.4 PRIVILEGES FOR DENTISTS AND PODIATRISTS AND CLINICAL PSYCHOLOGISTS

Privileges granted to dentists, podiatrists, or clinical psychologists shall be in the scope of their license and in accordance with their training, experience, demonstrated competence, and judgment.

A. Admissions

A dentist, podiatrist or clinical psychologist member with clinical privileges may admit patients to the hospital in accordance with procedures set forth in the medical staff and department rules and regulations. They must designate a physician member to perform the patient's history and physical, and to assume responsibility for the necessary medical care of the patient through the hospital stay. The dentist, podiatrist, or clinical psychologist member is responsible for the care of the patient in their specialty, including the relevant history (and, if applicable, the relevant

portion of the physical examination) and all appropriate elements of the patient's medical record. The dentist, podiatrist, or clinical psychologist may write orders within the scope of their license and within the scope of clinical privileges granted (to the extent and in a manner consistent with the medical staff rules and regulations).

B. Surgery

The scope and extent of surgical procedures that an individual dentist or podiatrist member may perform must be specifically defined and granted by the board of directors in the same manner as surgical privileges are defined and granted to physician members of the medical staff. Dentists shall practice surgery within the Department of Surgery. Podiatrists shall practice surgery within the Department of Orthopedic Surgery.

6.5 TEMPORARY CLINICAL PRIVILEGES

A physician, dentist, podiatrist, psychologist, or other practitioner who is not a member of the medical staff may request temporary privileges under the following circumstances:

A. Circumstances

Upon documented concurrence of the chairman of the department where the privileges will be exercised, the chairman of the credentials committee, the president of the staff, and the administrator may grant temporary privileges in the following circumstances:

1. Pendency of Application

Upon receipt of a completed application including a request for specific temporary privileges, and after the application has been processed to the point of letters of reference having been received, proof of professional liability insurance having been received, written reports having been received from the Medical Board of California, the American Medical Association, and the National Practitioner Data Bank, ~~an~~ **a possible** interview having been conducted by the department chairman or designee, and upon favorable recommendation of the credentials committee chair, an appropriately licensed applicant may be granted temporary privileges. Such temporary privileges will expire as of the date of the next scheduled credential committee meeting unless extended by the credential committee to remain in effect pending further action by the MEC and the board of directors. In exercising such privileges, applicants shall act under the monitoring of the chairman of the department to which they are assigned or designee in accordance with the conditions specified in Section 6.5-B. If the applicant requests temporary privileges in more than one department, approvals must first be obtained from the appropriate chairmen.

Temporary privileges may also be granted following receipt of a timely and complete application for reappointment as provided in Section 5.8.K. In such cases, temporary privileges shall take effect as of the expiration of the prior term of appointment or such other date as may be specified.

Temporary privileges are granted for a period not to exceed ninety (90) days with subsequent renewal, subject to reassessment under Section 6.5-B, not to exceed another sixty (60) days.

2. Care of Specific Patients

Upon receipt of a request for specific temporary privileges, an appropriately licensed practitioner for whom adequate assurance or confirmation has been provided as to professional liability insurance, current competence based on qualifications, ability and judgment to exercise the privileges requested who is not an applicant for membership may be granted temporary privileges when good cause exists for the care of one or more specific patients **not to exceed sixty (60) days**. Where feasible, reports on the practitioner will be obtained from the Medical Board of California and the National Practitioner Data Bank before such privileges are granted. Such privileges shall be restricted to the treatment of not more than three (3) patients during a calendar year, after which such practitioner shall be required to apply for membership on the medical staff before being allowed to attend additional patients.

3. Locum Tenens

a. An appropriately licensed practitioner of documented current competence who is serving as a locum tenens for a member of the medical staff may, without applying for membership on the staff, request in writing specific temporary privileges. Accompanying this written request shall be a completed application form. Such person may attend only patients of the member(s) for whom that person is providing coverage for a period not to exceed sixty (60) consecutive days unless the MEC recommends a longer period for good cause.

b. Practitioners who are serving as locum tenens may not admit their own patients to the hospital and all admissions shall be under the name of the practitioner for whom they are serving locum tenens.

B. Conditions

1. Temporary privileges shall be granted only when the information available reasonably supports a favorable determination regarding the requesting practitioner's qualifications, ability and judgement to exercise the privileges requested. Special requirements of consultation and reporting may be imposed by the chairman of the department responsible for monitoring and proctoring a practitioner granted temporary privileges. Except as allowed by the president of the medical staff for good cause, before temporary privileges are granted, practitioners must acknowledge in writing that they have received, or been given access to, and read the medical staff bylaws, rules and regulations and that they agree to be bound by the terms thereof in all matters relating to their temporary privileges including rules and regulations of the designated medical staff department. If granted temporary privileges, applicants shall act under the supervision of the chairman of the department to which they have been assigned, and shall ensure that the chairman, or the

chairman's designee, is kept closely informed as to the applicants' activities within the hospital.

2. Temporary privileges shall automatically terminate at the end of the designated period, unless earlier terminated by the MEC upon recommendation of the department chairman or credentials committee, or as otherwise provided in these bylaws.

3. Requirements for proctoring and monitoring, including but not limited to those in Section 6.3, shall be imposed on such terms as may be appropriate under the circumstances upon any member granted temporary privileges by the president of the staff after consultation with the departmental chairman or his designee.

C. Termination

Temporary privileges may at any time be terminated by the president of the staff with the concurrence of the chairman of the department or their designees. In such cases, the appropriate department chairman or, in the chairman's absence, the president of the staff shall assign a member of the medical staff to assume responsibility for the care of such practitioner's patient(s). The wishes of the patient shall be considered in the choice of a replacement medical staff member.

D. Rights of Practitioner

A practitioner shall be entitled to the procedural rights afforded by Article VIII when temporary privileges are denied, reduced, suspended or terminated for medical disciplinary cause or reason, as provided in Section 8.2-N.

6.6 EMERGENCY PRIVILEGES

In the case of an emergency, any member of the medical staff, to the degree permitted by his or her license and regardless of department, staff status, or clinical privileges, shall be permitted to do everything reasonably possible to save the life of a patient or to save a patient from serious harm. The member shall make every reasonable effort to communicate promptly with the department chairman concerning the need for emergency care and assistance by members of the medical staff with appropriate clinical privileges, and once the emergency has passed or assistance has been made available, shall defer to the department chairman with respect to further care of the patient at the hospital.

EXHIBIT 5

UNITED STATES DISTRICT COURT FOR THE

NORTHERN DISTRICT OF CALIFORNIA

COYNESS L. ENNIX, JR., M.D., as an individual and in his representative capacity under Business and Professions Code Section 17200, et seq.,

Plaintiff,

vs.

RUSSELL D. STANTEN., M.D., LEIGH I.G. IVERSON, M.D., STEVEN A. STANTEN, M.D., WILLIAM M. ISENBERG, M.D., Ph.D., ALTA BATES SUMMIT MEDICAL CENTER, DOES 1 through 100, inclusive,

Defendants.

COPY

Case No: 07-2486

TRANSCRIPT MARKED CONFIDENTIAL

DEPOSITION OF COYNESS L. ENNIX, JR., M.D.

VOLUME II, pages 130 to 354

Saturday, May 26, 2007

10:11 a.m.

Taken at Kauff, McClain & McGuire
One Post Street
San Francisco, California

PREFERRED REPORTERS
Certified Shorthand Reporters
201 E. Watmaugh Road
Sonoma, California 95476
707-938-9227

Reported By: Linda Vaccarezza, RPR, CSR #10201

A Such a thing? No. 01:24:47p

MS. MCCLAIN: May I have this marked as next 01:24:50p
in order, please. 01:24:55p

(Exhibit 19 was marked for identification.) 01:25:06p

BY MS. MCCLAIN: 01:25:07p

Q Do you recognize this document as part 01:25:07p
of a medical record of a patient -- 01:25:49p

A Yes. 01:25:53p

Q -- of yours? 01:25:53p

A That's my writing. I recognize the 01:25:54p
writing, the patient and the incident. 01:25:58p

Q The writing on the first page of this 01:25:59p
exhibit is all yours; is that correct? 01:26:03p

A Yes. Looks like my writing. 01:26:05p

Q The writing on the second page of this 01:26:14p
exhibit starting from the line "5/6/05 CT" is all 01:26:16p
yours, correct? 01:26:22p

A It appears to be my writing. 01:26:23p

Q The writing above that line on the 01:26:26p
second page is not your writing; is that right? 01:26:27p

A No, that's not my writing. 01:26:29p

Q Is it correct that the note on the first 01:26:32p
page, bearing the date 5/5/05, was actually made 01:26:38p
by you on May 6th, 2005? 01:26:42p

A That's correct. 01:26:45p

STATE OF CALIFORNIA)
COUNTY OF SONOMA)

I, LINDA VACCAREZZA, a Certified Shorthand Reporter of the State of California, duly authorized to administer oaths pursuant to Section 2025 of the California Code of Civil Procedure, do hereby certify that

COYNESS L. ENNIX, JR., M.D.,

The witness in the foregoing examination, was by me duly sworn to testify the truth, the whole truth and nothing but the truth in the within-entitled cause; that said testimony of said witness was reported by a disinterested person, and was thereafter transcribed under my direction into typewriting and is a true and correct transcription of said proceedings.

I further certify that I am not of counsel or attorney for either or any of the parties in the foregoing examination and caption named, nor in any way interested in the outcome of the cause named in said caption.

Dated the 27th day of May, 2007

LINDA VACCAREZZA, RPR, CSR #10201

EXHIBIT 6

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

- - -

COYNESS L. ENNIX, JR., M.D.,

Plaintiff,

vs.

ALTA BATES SUMMIT MEDICAL CENTER,

Defendant.

No.: C07-2486WHA

DEPOSITION OF

EUGENE SPIRITUS, M.D.

ORANGE, CALIFORNIA

FEBRUARY 26, 2008

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REPORTED BY: GLENNA J. McNEALY, CSR NO. 9138

FILE NO.: A2015E9

committee to initiate a peer review proceeding?

MR. EMBLIDGE: Vague as to "initiate" and incomplete hypothetical.

THE WITNESS: If the president of medical staff became aware of a quality or a safety issue, we would certainly have the right to bring it before the executive committee to discuss as to what the committee should do.

BY MR. VANDALL:

Q. I understand. So it would be within the discretion of the medical staff president to determine whether or not to raise a peer review issue directly with a medical executive committee; is that right?

A. It's absolutely within his prerogative, as it is every member of the medical staff.

Q. Have you participated in peer reviews of physicians outside the context of UCI Medical Center?

A. When I was at St. Joseph's Hospital as a member of the medical staff, I believe I was on one peer review. I was on one -- I believe I was on one ad hoc committee for peer review.

Q. Other than --

A. Other than that, I was involved in peer review at the department level reviewing charts within the department.

Q. At the St. Joseph's Hospital?

CERTIFIED COPY CERTIFICATE

I, GLENNA J. McNEALY, CSR No. 9138, a Certified Shorthand Reporter in the State of California, certify that the foregoing pages, 1 through 170, constitute a true and correct copy of the original deposition of EUGENE SPIRITUS, M.D., taken on February 26, 2008.

I declare under penalty of perjury under the laws of California that the foregoing is true and correct.

Dated this 6th day of March, 2008.

GLENNA J. McNEALY, CSR No. 9138

EXHIBIT 7

CONFIDENTIAL

5/12/05
Confidential note to file of Coyness Ennix, MD

I met this afternoon with Joan Shields, RN, in the ICU, to discuss the letter, dated 5/10/05, that she submitted to the Medical Staff at Dr. Ennix's request. I asked her how she came to write this letter. She told me that Dr. Ennix came to the unit and told her: "Joni, I'm in a world of trouble and you're the only one who can help me." She went on to say that Dr. Ennix told her that he had been suspended for not seeing a pt on 5/5/05, on which day she was the nurse of record for the pt. He asked that she write a letter verifying that he had seen the pt in the unit. I asked if he had threatened, coerced, or in any other way, influenced her to write the letter. She said that he had not.

I asked her some specifics regarding her letter. First, when she stated: "He came in the patient's room to assess the patient..." did that mean that he did a physical exam, listening to the heart and lungs, examining the chest tubes, the wound, etc? She replied that "actually, I didn't see him examine the patient at all. He may have done so at some other time during the day when I wasn't in the room. While I was there, we talked about the patient, I told him about my concerns—this patient had a very rocky night. I was still concerned about his bleeding and that he was nowhere near ready for extubation." After you finished expressing your concerns, what happened? "We talked about closely monitoring the patient, and holding off on extubation. He then went to the desk and I asked him to sign the telephone orders, which he did before leaving the unit to go to surgery." She went on to say that she spoke to Dr. Ennix a couple of more times throughout the day regarding the pt's status.

Lastly, I asked if this scenario was typical or atypical for Dr. Ennix making rounds on POD#1 following open heart surgery, in her experience. She said, "Unlike the other cardiac surgeons, Dr. Ennix gives us a lot of latitude in managing the patients. The other doctors, both his partners and the Kaiser doctors, write very specific orders and don't ask us our opinions very much about how to manage them."

William M. Isenberg, MD

EXHIBIT 8

From: Smithline, Neil
Sent: Monday, May 2, 2005 1:59 PM
To: McCluney, Suzanne <suzanne-mccluney@mcg.com>
Subject: FW: Dr E Report

-----Original Message-----
From: harryshulman@dwt.com [mailto:harryshulman@dwt.com]
Sent: Monday, May 02, 2005 10:33 AM
To: Isenberg, William, M.D.; Smithline, Neil
Cc: Weaver, Karen
Subject: RE: Dr E Report

Bill,

I am not finished reading the draft yet, but I am working on it. Neil called me about your e-mail, and I told him that the problem with him including the comment about non-compliance with the Rules and Regulations is that NMA does not have the Rules and Regulations, so the reference would not be appropriate in the report. It would go beyond clarification and add a substantive observation that they would not make on their own. The three of us should talk later today.

Harry

-----Original Message-----
From: Isenberg, William, M.D. [mailto:IsenbeW@sutterhealth.org]
Sent: Monday, May 02, 2005 7:28 AM
To: Smithline, Neil
Cc: Shulman, Harry; Weaver, Karen
Subject: RE: Dr E Report

Good morning Neil,
Here is a red-lined version with a suggestion re: the timeliness issue of med rec completion on p28. Bill

-----Original Message-----
From: Smithline, Neil [mailto:Neil.Smithline@mercer.com]
Sent: Friday, April 29, 2005 1:04 PM
To: Isenberg, William, M.D.; Weaver, Karen
Cc: McCluney, Suzanne; Herman, Jennifer
Subject: Dr E Report

Bill, Karen

Here is a draft report for your review. After you have had a chance to review it, please call me to discuss.

Thanks

Neil